

### **REMARKS**

The applicants and their representatives have fully considered the Office Action of May 19, 2004 and provide the following remarks in conjunction with the amendments presented above. In light of the amendments and in view of the remarks, withdrawal of all rejections is respectfully requested.

Preliminarily, it is noted that claims 1-4, 6, and 26-30 are pending in this application. For the record, however, it is noted that although the cover sheet of the Office Action indicates that claims 1 "through" 6 are pending, claim 5 was canceled in the Preliminary Amendment of August 6, 2003. Therefore, the following remarks are responsive to pending claims 1-4, 6, and 26-30. Claims 1 and 26 are the only independent claims and have both been amended. The double patenting and prior art rejections are addressed below.

#### **Double Patenting**

Claims 1-3, 6, 26-28, and 30 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 8, 18, and 24 of U.S. Patent No. 6,670,171 (Carll). In order to advance prosecution of this application, and without conceding that the subject matter claimed herein is rendered obvious by the Carll patent, a terminal disclaimer is submitted herewith. Accordingly, this rejection has been obviated.

Assignment documents were made of record June 14, 2004, documenting the transfer of ownership interest from Wheaton USA, Inc. to Alcan Packaging Pharmaceutical and Personal Care Inc. in both the pending case and the Carll reference. The terminal disclaimer therefore reflects this change.

#### **Discussion of Prior Art and the Patentability of Pending Claims**

Claims 1, 3, 4, 6, 26, and 28-30 have been rejected under 35 U.S.C. §103(a) in view of GB 2,202,549 (Whitney) and U.S. Patent No. 5,375,926 (Omasa). Claims 2, 6, 27, and 30 have been rejected under 35 U.S.C. §103(a) in view of Whitney, Omasa, and U.S. Patent No. 5,288,296 (McCabe). For the reasons presented below and in light of the preceding amendments, withdrawal of these rejections is earnestly solicited.

The May 19, 2004 Office Action acknowledges that Whitney does not teach an impeller attached to said headplate "such that it [impeller] does not rotate about its central axis." To fill this void, the Office Action uses Omasa for an alleged teaching of an impeller which is "attached to the headplate (12) of the vessel such that the shaft does not rotate about its central axis (See Figure 10)." The applicants respectfully submit that this combination is improper for at least two reasons. First, there is no motivation in either reference to combine it with the other. Second, even if the two were combined, such a combination would not yield that which is presently claimed, because Omasa does not teach a shaft having a rotational movement restricted *solely* below the headplate.

### **No Motivation to Combine**

Whitney was cited for its teaching of a pre-sterilized cell culture vessel which includes a headplate and a collapsible bag sealed to an edge of the headplate. Whitney is specifically directed to a fermenter and it explicitly teaches that its reactor be capable of folding "for sterilization or storage." Omasa, on the other hand, shows an impeller for mixing in industrial processes (see col. 1, lines 10-14) in which the shaft (and thus its impeller) oscillates vertically in and out of the vessel (see Fig. 10). In doing so, a portion of Omasa's shaft (3) alternately enters and exits the vessel. Such an impeller is not suitable for use in a sterilized vessel for which a sterile mixing environment is desired. Thus, Omasa's impeller apparatus could not be used in the present invention because it would quickly destroy the sterile environment inside the vessel and contaminate the contents. Moreover, the applicants submit that, if anything, Whitney teaches away from the use of an impeller such as that disclosed by Omasa.

### **Even if the References Were Combined, the Vessel Resulting from the Combined Elements Would Not Yield the Present Invention**

The Office Action cites that such a combination would be "avoiding the drawbacks associated with rotational agitators." (See Omasa, col. 1, lines 34-38). However, such a combination yields the very problem the presently claimed invention seeks to solve. One of the drawbacks associated with rotational agitation, not eliminated by combining the cited references, is that of contamination. In fact, if combined, the resulting invention would nonetheless contribute to the problem addressed by the present invention.

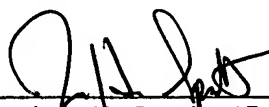
Specifically, claims 1 and 26 have been amended to recite that the disposable vessel is defined by "a shaft extending from said headplate into said collapsible bag wherein said shaft does not extend above said top of said headplate." This limitation has been added to both independent claims to emphasize that the shaft of the present invention does not move out of the vessel. By staying beneath the headplate and not exiting the vessel, the possibility for contamination is eliminated because the shaft does not come into contact with anything outside the sterilized environment. It is this very possibility of contamination that exists in Omasa, whereby Omasa discloses a shaft oscillating vertically in and out of the vessel, thus contributing to the very problem the claimed invention proposes to solve. Specifically, the device disclosed in Omasa provides for a portion of the shaft that alternately enters and exits the vessel by periodically extending above the headplate.

Applicants respectfully assert, therefore, that amended claims 1 and 26, and their respective dependent claims, namely 2-4, 6, and 27-30, define a patentable feature which is neither taught nor suggested in Omasa, Whitney, or McCabe. It is respectfully asserted, therefore, that these amendments make even more clear a patentable distinction between the presently claimed invention and that of Omasa, Whitney, or McCabe.

### Conclusion

For these reasons, the applicants respectfully request withdrawal of the rejection of claims 1-4, 6, and 26-30 and an indication of their allowance. It is noted that claims 2-4, 6, and 27-30 all depend, either directly or indirectly, from claims 1 and 26, respectively. If the Examiner believes that further communication would aid in prosecution, he is invited to call the applicants' below-named signatory to discuss the application.

Respectfully submitted,



Jonathan H. Spadt, 45,122  
Attorney for Applicant

JHS/

Dated: August 10, 2004

☒ P.O. Box 980  
Valley Forge, PA 19482  
(610) 407-0700

☐ P.O. Box 1596  
Wilmington, DE 19899  
(302) 778-2500

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 18-0350 of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

August 10, 2004

